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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,735	10/25/2001	Liat Tsoref	082/02329	9997

26418 7590 09/10/2003

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EXAMINER	
JAWORSKI, FRANCIS J	
ART UNIT	**PAPER NUMBER**
3737	8

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,735	Applicant(s) TSOREF ET AL.	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The terminology "ossification actuated " is not understood. Applicants appear to be applying this term to any age of patient, and apart from any developmental meaning since ossification in and of itself occurrs not only in association with endochondral ossification or replacement of cartilage with bone such as in ossification centers within the epiphyses in youth but also after early adulthood in fracture remodelling and stress remodelling due to weight changes. Applicant also appears to be using this term to apply to situations involving net bone resorption such as the diminution of bone mass which occurrs with osteoporosis, see specification col. 3 lines 21 - 25, since the contention is made that an ordinary osteoporosis device may be re-tabled to output 'bone age' rather than a conventional measurement associated with bone integrity loss/fracture risk. This therefore broadens the term to mean 'undergoing bone change', meaning 'not limited to maturation or deposition processes unless otherwise stated', and the Examiner has adopted this meaning as the 'broadest reasonable interpretation' for examination purposes.

Claim 41 is objected to as being run-on. Suggest delete "predict one or more of" in one instance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-25, 27 - 29, 36-38, 40, 46, 49-50, 52-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Sarvazyan et al (US6468215). Sarvazyan et al teaches an ultrasound transmission system including transducer 22 for assessing skeletal age in the growth regions of bone undergoing primary and secondary ossification, see col. 3 esp. lines 46 - 49.(Claims 1, 2, 9, 18) with evaluation of bones (plural) col. 1 line 58 (claim 3), fibro-cartilage, soft tissue and cartilage all being inherent in the anatomic definition of the epiphyseal plate at the diaphyseal end-zone or 'growth region' (claims 4-6, 10), meaning that applicants are using equivalent anatomic terms by definition under the terminology set forth in the reference col. 2 to describe childhood skeletal maturation, and evaluation is additionally of the long bone central areas or primary ossification centers.(claim 7). The term 'tarsus' includes the heel as taught in the patent col. 2 line 14. (Claim 8). The femur is one of the body's 'long bones' by definition, see also col. 3 line 44.(Claim 11). Two or more measurements along the bone and in a fixed direction using a movable gantry as per Fig. 2 define a profile graph for a given bone, col. 4 lines 44-46. (Claims 12-13, 15, 17, 49-50) under control of microcontroller 37 (claim 52).. Different bones are used

for symmetry comparisons, see col. 7 lines 20-21, whereupon the ensonation direction has to be reversed to perform the left-to-right (opposite limb measurement) or vice-versa (Claims 14,16). Velocity of sound in tissue and bone is measured as per col. 6 lines 55 - 62 (claims 19, 23) as is broadband ultrasound attenuation, col. 5 lines 63-65 together with col. 6 lines 62-66. (Claims 20,22,24, 53). Dispersion is used to compute bone flexural attributes, see col. 7 lines 32-37. (Claim 21). Monitoring is to adulthood- maturation see col. 1 lines 26-31. (Claim 25). Multi-beam operation and scanning are performed, see col. 4 bottom, Figs. 1,2 and 29, 32 (Claims 27-28).Different spectral compositions are transmitted axially into the bone, see col. 5 lines 58 - 65. (Claim 29). A graphical database of multiple measurement profiles is generated and includes norms for gender and age, see col. 7 lines 14-21. (Claims 36-38, 40, 46). Imager 13 indicates appropriate transducer placement as well as graphical visual display related to bone age assessment (claims 54-56). Controllers 12 and 13 are networked together, col. 6 lines 40-44. (claim 57).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 26, 30-35, 39, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarvazyan et al . It would have been obvious in view of the latter to compare results with other modalities since col. 1 lines 45 - 58 acknowledge that these also produce results independent of body size per se. (Claims 26, 31). Since skin thickness varies, it would be inherently obvious to re-position the limb or test apparatus radially towards a more accessible profile site in the col. 5 technique. (Claims 30,51). Implicit in the col. 3 item 5 desideratum of determining skeletal age by cessation of growth zones is the known formulaed relationship for same since the patentee is invoking knowledge of the artisan as to how to make this correlation via age and gender tabulations in col. 7.. (Claims 32,35). See application of patent against claims 20-24 supra (claims 33-34). It would have been inherently obvious to perform multiple measurements of the above-discussed one or more measurement sites in order to pediatrically track a child to maturation (claim 39).

5. Claims 41-45, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarvazyan et al as applied to claim 1 above, and further in view of applicants' specification, since page 1 thereof notes that application of skeletal age assessment to prediction of adult stature and diagnosis and monitoring of skeletal growth problems using skeletal age measurements was in and of itself well-known by a variety of database bone feature estimating techniques..(Claims 41-43, 59-61). Growth hormone was well-known to treat growth shortfall. (Claim 44).

6. The particular maladies causing bone age to fall behind would be well-known to the endocrinologist. Applicants have indicated no criticality to diagnosis of a particular bone growth delay malady or specific instructions as to how to detect same. (Claims.45, 48-49).

7. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarvazyan et al as applied to claim 49 above, and further in view of Kaufman et al (US5651363). It would have been obvious in view of the latter to utilize a neural networkas per col. 7 lines 43-48 to perform bone feature analysis since this technique is superior to human diagnosis with respect to multiple values being assessed.

8. Coleman et al (US6306089) and Oonuki (US6454712) are variously directed to fetal skeletal parameter assessments.

9. The Abstract requires revision to avoid legal phraseology such as claim phraseology.

10. Any inquiry concerning this communication should be directed to Examiner Francis J. Jaworski at telephone number 703-308-3061..

Francis J. Jaworski
Primary Examiner

FJJ:fjj

9-3-03